

In the United States Court of Federal Claims

No. 95-215 V

(Filed March 24, 1999)

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MELISSA TROJANOWICZ, by her parents  
and next friends, LORI TROJANOWICZ  
and JOHN TROJANOWICZ,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,  
Respondent.

Vaccine Act, 42 U.S.C. §§ 300aa-  
11(a), 11(c), 13(a), 13(b);  
causation in fact; burden of proof  
on motion for review challenging  
determination of no causation in fact.

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Laurie Trojanowicz<sup>(1)</sup> and John Trojanowicz, Carbondale, Pennsylvania, pro se.

Mark W. Rogers, with whom were Frank W. Hunger, Assistant Attorney General,

Helene M. Goldberg, Director, John Lodge Euler, Deputy Director, Gerard W. Fischer, Assistant  
Director, U.S. Department of Justice, Washington, DC, for respondent.

OPINION

HEWITT, Judge

Petitioners seek review in the United States Court of Federal Claims of a special master's decision that denied them compensation under the National Childhood Vaccine Injury Compensation Program. Laurie and John Trojanowicz, who are proceeding in this court pro se, are seeking compensation for injury sustained by their daughter, Melissa Trojanowicz, after she received a diphtheria-pertussis-tetanus ("DPT") vaccination from her physician on March 2, 1994. On July 1, 1998, the special master issued a decision denying the petition and concluding that there was not a preponderance of evidence supporting petitioners' assertion that the DPT actually caused their daughter's chronic inflammatory demyelinating polyradiculoneuropathy ("CIDP"). Pursuant to 42 U.S.C. §§ 300aa-12(e), petitioners filed a motion in this court seeking review of the special master's decision. For the reasons set forth below, petitioners'

motion for review is denied and the special master's decision is affirmed.

## I. BACKGROUND

Melissa Trojanowicz was a seemingly healthy child prior to the administration of the DPT vaccine given just prior to her fifth birthday.<sup>(2)</sup> On the same day the vaccination was administered, Melissa's pediatrician noted that Melissa had "no problems." Trojanowicz v. Secretary of Dep't of HHS, No. 95-215 V, 1998 WL 774338, at \*1 (Fed. Cl. July 1, 1998) (reissued for publication October 16, 1998). At some point following the administration of the vaccination, Melissa's motor skills deteriorated. Upon examining Melissa and noting that her condition may be "Gillian Barre," [sic] her pediatrician, Dr. Neal Davis, referred her to the Alfred I. duPont Institute. *Id.* at \*2 (quoting Petitioner's Exhibit 6, at 2). At the duPont Institute, chief neurologist, Dr. Harold Marks, stated that Melissa was most likely suffering from Guillain-Barre Syndrome ("GBS"). Dr. Marks later determined that the correct diagnosis is CIDP. *Id.* (citing Petitioner's Exhibit 20, at 2).

CIDP is not found on the Vaccine Injury Table. 42 U.S.C. § 300aa-14(a). The Vaccine Injury Table lists vaccines covered by the Vaccine Act. When a particular injury is listed under a vaccine on the Table, the petitioner is afforded a presumption that the vaccine caused the injury. When a particular injury is not found on the Vaccine Injury Table, petitioners must prove by a preponderance of the evidence that a particular injury was caused in fact by a vaccine listed on the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (I). The court of appeals has stated that "an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." Shyface v. Secretary of Dep't of

HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).<sup>(3)</sup> In order to show that a vaccine was a substantial factor in bringing about the injury, the petitioner must show 'a medical theory causally connecting the vaccination and the injury.'" Shyface, 165 F.3d at 1352-53 (quoting Grant v. Secretary of Dep't of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). Therefore, petitioners attempted to prove that Melissa's CIDP was caused in fact by the DPT vaccine administered to her on March 2, 1994. To prove their case, petitioners employed Dr. Charles Bean.

Dr. Bean focused on a component of the DPT vaccination, tetanus toxoid. While he acknowledged that there are no reported cases associating CIDP with tetanus toxoid, he pointed to the fact that there have been known associations between tetanus toxoid and acute inflammatory demyelinating polyradiculoneuropathy ("AIDP").<sup>(4)</sup> Therefore, Dr. Bean attempted to analogize CIDP with AIDP to show that, like AIDP, DPT has a known association to CIDP. He posited that they "have clinically similar symptoms, that their pathogenesis is similar, they are both inflammatory neuropathies and thus concluded that they can be analogized for purposes of causation." Trojanowicz, 1998 WL 774338, at \*2. To strengthen his argument, Dr. Bean also cited to the proximity in time between the onset of Melissa's injury and the administration of the vaccination as well as the lack of any other known cause in attempting to support his causation theory.<sup>(5)</sup>

Respondent's expert, Dr. Barry G.W. Arnason, disagreed with the assertions of Dr. Bean. Dr. Arnason stated that epidemiological studies of millions of people failed to find a connection between AIDP and tetanus toxoid or other vaccinations. *Id.* at \*2 (citing Respondent's Exhibit A, at 4.) In addition, the medical literature fails to support the assertions of petitioners and Dr. Bean. In fact, the special master determined that medical literature actually refutes Dr. Bean's assertions regarding similar causative agents between AIDP and CIDP. After thorough consideration, the special master concluded:

Despite Dr. Bean's good faith efforts to support this case, it is logically and legally impermissible to

extrapolate from similarities in pathogenesis to a conclusion of shared causative agents in light of the lack of support from the available medical literature, or some type of objective support from the relevant medical community, and in the face of medical literature indicating strong differences in antecedent events.

Trojanowicz, 1998 WL 774338, at \*5. Following the direction provided by the Supreme Court,<sup>(6)</sup> the special master determined Dr. Bean's testimony to be nothing more than "unsupported speculation." *Id.* at \*6. Because petitioners failed to prove by a preponderance of the evidence that Melissa's CIDP was caused by the DPT vaccine, the special master dismissed the case.

## II. DISCUSSION

### A. Petitioners' Motion for Review

The Vaccine Rules, found in Appendix J of the Rules of the United States Claims Court,<sup>(7)</sup> provide the procedures to be followed in obtaining review of a decision by a special master. Vaccine Rule 24 requires a memorandum of numbered objections to accompany a motion for review.<sup>(8)</sup> Although petitioners' motion for review failed to meet the requirements of Rule 24, this court has stated that "the right of persons to represent themselves is well recognized as is also the practical impossibility that such persons can be expected to prepare pleadings according to the formal requirements that can be demanded of attorneys . . . ." Clinton v. United States, 191 Ct. Cl. 604, 605 (1970). The Supreme Court has taken the view that allegations made in a pro se complaint are to be held to "less stringent standards than formal pleadings drafted by lawyers." Haines v. Kerner, 404 U.S. 519, 520-21, 92 S. Ct. 594, 595-96, 30 L. Ed. 2d 652 (1972).

Although the form of petitioners' motion for review may be lacking, petitioners are not relieved of the burden of ensuring that the substance of their motion adequately states the merits of a claim upon which this court may grant relief. Davis v. United States, 36 Fed. Cl. 556, 558 (1996). As stated in Henkel v. Secretary of Dep't of HHS, 42 Fed. Cl. 528 (1998), "nothing in the Vaccine Act displaces the proposition that a party must make its case on review. The judge is not responsible for scouring the record for factual mistakes or ferreting out facts that support a position that either side or the special master has overlooked." *Id.* at 530. Moreover, the United States Court of Claims has previously stated in a case involving record review that "the plaintiff has the burden of establishing the fact that the record does not support the Board's finding. This it has failed to do. It is not the court's function to supply this deficiency by an independent excursion along the administrative trail." *Id.* (quoting Sundstrand Turbo v. United States, 182 Ct. Cl. 31, 60, 389 F.2d 406, 422-23 (1968)).

In light of the above decisions, the court accepts the petitioners' motion for review as filed and examines the merits of their appeal. Petitioners have provided little upon which this court can base its review of the special master's decision. Petitioners simply failed to state any specific objection to the determination of the special master aside from the general statement that petitioners believe the special master's decision to be "wrong." Motion to Review, at 1.

### B. Standard of Review

As established by 42 U.S.C. §§ 300aa-13(a)(1)(A), the burden is on petitioners to demonstrate by a preponderance of the evidence that Melissa's CIDP was caused by the DPT vaccination. Under the Vaccine Act, the special master determines whether or not a particular petitioner is due compensation based on the merits of his or her case. 42 U.S.C. § 300aa-12(d)(3). The special master's decision is based on the "record as a whole" including "relevant medical and scientific evidence." 42 U.S.C. §§ 300a-13

(a) and (b).

Review by the Court of Federal Claims of a special master's decision is quite limited. Carraggio v. Secretary of Dep't of HHS, 38 Fed. Cl. 211, 217 (1997). A special master's findings of fact and conclusions of law will be set aside only if the court finds them "to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 42 U.S.C. § 300aa-12(e)(2)(B). It is not up to the court to substitute its own judgment for that of the special master in the absence of "clear error" on the part of the special master. Misasi v. Secretary of Dep't of HHS, 23 Cl. Ct. 322, 325 (1991) (citing Hyundai Electronics Indus. Co. v. ITC, 899 F.2d 1204, 1209 (Fed. Cir. 1990)). "If the special master has considered the relevant evidence in the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Burns v. Secretary of Dep't of HHS, 3 F.3d 415, 416 (Fed. Cir. 1993).

In resolving the dispute presented before him, the special master evaluated the facts, the testimony given by the medical experts, Dr. Bean and Dr. Arnason, and relevant medical literature. The special master had an opportunity to question the medical experts in regard to findings in the medical literature. Based upon his examination, the special master found the scientific evidence to be more heavily weighted in support of the respondent's position. In their motion for review, petitioners have not attempted to show that the special master's decision was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. Under the standard of review applicable to this case, the court must uphold the findings of the special master and sustain his decision under Vaccine Rule 27(a). 42 U.S.C. § 300aa-12(e)(2)(A).

### III. CONCLUSION

The court has thoroughly reviewed the record and finds no basis for overturning the decision of the special master. The special master's determination that there is no medical basis for drawing a causal connection between DPT and CIDP is well founded and does not constitute an abuse of the special master's discretion under the Vaccine Act. Petitioners have not shown that the special master's findings of fact and conclusions of law are arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. For the reasons set forth above, the special master's July 1, 1998, decision is AFFIRMED. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

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EMILY C. HEWITT

Judge

1. The case was docketed for proceedings before the special master and, accordingly, by the Clerk of the Court in connection with this appeal, as "Melissa Trojanowicz by her parents . . . Lori Trojanowicz and John Trojanowicz." We note that Ms. Trojanowicz signed the petition for review as *Laurie* Trojanowicz.
2. In his decision, the special master noted the existence of dispute regarding factual matters related to the onset of Melissa's CIDP. Because the case was decided based on the medical arguments presented, the special master decided that it was unnecessary to resolve the factual issues. Therefore, the special

master relied on the facts found in the petitioners' amended petition. The court agrees with the special master that in resolving this dispute it was unnecessary to resolve the factual questions raised by the case. Without a medically supported causal connection between DPT and CIDP, petitioners' case failed for lack of establishing causation in fact. Trojanowicz v. Secretary of Dep't of HHS, No. 95-215 V, 1998 WL 774338, at \*6 (Fed. Cl. July 1, 1998) (reissued for publication October 16, 1998). Therefore, it was, and still is, unnecessary to reach a conclusion regarding the exact timing of the onset of Melissa's CIDP.

3. Because the Vaccine Act is not specific in regard to the causation requirements in a non-Table case, the court of appeals in Shyface employed the approach of the Restatement (Second) of Torts §§ 431 - 433. The court found that this method of analysis provides both a uniform approach to vaccine cases and is in accord with the legislative history of the Vaccine Act. Shyface, 165 F.3d at 1351. The Restatement provides:

#### § 430. Necessity of Adequate Causal Relation

In order that a negligent actor shall be liable for another's harm, it is necessary not only that the actor's conduct be negligent toward the other, but also that the negligence of the actor be a legal cause of the other's harm.

#### § 431. What Constitutes Legal Cause

The actor's negligent conduct is a legal cause of harm to another if

(a) his conduct is a substantial factor in bringing about the harm, and

(b) there is no rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm.

#### § 432. Negligent Conduct as Necessary Antecedent of Harm

(1) Except as stated in Subsection (2), the actor's negligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent.

(2) If two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about.

#### § 433. Considerations Important in Determining Whether Negligent Conduct is Substantial Factor in Producing Harm

The following considerations are in themselves or in combination with one another important in determining whether the actor's conduct is a substantial factor in bringing about harm to another:

(a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it;

(b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible;

(c) lapse of time. Restatement (Second) of Torts §§ 430 - 433 (1963-1964).

The Restatement clarifies the meaning of "substantial factor" by stating that a particular actor does not have to be the sole or predominant cause of harm. Id. at § 430 cmt. d.

4. Trojanowicz, 1998 WL 774338, at \*2.

5. Although temporal association between an injury and a vaccination is sufficient to establish legal causation in Table cases, it is not sufficient to establish causation in fact. Grant v. Secretary of Dep't of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Evidence in the form of expert medical testimony or scientific studies is necessary. Shyface, 165 F.3d at 1351. Moreover, the Vaccine Act requires two separate inquiries under the statute. The first is whether a causal connection between the vaccine and the injury has been demonstrated. 42 U.S.C. § 300aa-13(a)(1)(A). The second inquiry is satisfied if it is shown that the injury involved was not the result of factors unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B). The Grant court stated that "evidence showing an absence of other causes [alone] does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149.

6. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993), the Supreme Court provided a framework from which to evaluate scientific evidence. In order for a scientific theory to have scientific reliability, the Court noted the requirement of subjecting a particular theory to testing, peer review and publication. Id. at 593-94, 2796-97. Daubert also states the importance general acceptance within the scientific community in weighing the reliability of scientific evidence. Id. at 594, 113 S. Ct. at 2797.

7. The United States Claims Court is now known as the United States Court of Federal Claims. Federal Courts Administration Act of 1992, Pub.L. No. 102-572, § 902(a), 106 Stat. 4506, 4516.

8. Vaccine Rule 24 states:

The motion for review must be accompanied by a memorandum of numbered objections to the decision. This memorandum must fully and specifically state and support each objection to the decision. The memorandum shall cite specifically to the record created by the special master, e.g., to specific page numbers of the transcript, exhibits, etc., and should also fully set forth any legal argument the party desires to present to the reviewing judge.